# Trial Description

## Title

**Laparoscopic liver resection (LLR) with low central venous pressure (CVP) by anaesthesiological CVP reduction vs. LLR without CVP reduction in elective hepatic resection – A Randomized Controlled Trial**

## Trial Acronym

**[---]***

## URL of the trial

**http://-**

## Brief Summary in Lay Language

**One of the main goals of liver resections is to minimize intraoperative blood loss. Bleeding in the area of the transected liver contributes significantly to the total blood loss. Bleeding at the liver transection surface depends on the difference between intraabdominal pressure and central venous pressure (CVP).**
**Most liver surgeons use a low CVP (< 5 mmHg) to decrease blood loss in open and laparoscopic surgery (= standard of treatment). CVP reduction bears the risk of complications. In laparoscopic liver surgery, the pressure gradient between CVP and intraabdominal pressure is increased by applying the pneumoperitoneum.**
**So far there is no scientific certainty as to whether this is necessary in the context of minimally invasive surgery.**
**The aim of this study is to show that laparoscopic liver resection (LLR) with low CVP is equivalent to LLR without CVP reduction with respect to intraoperative blood loss. One group will be operated without lowering the central venous pressure (CVP) compared to the control group with lowering the ZVD (<5 mmHg).**

## Brief Summary in Scientific Language

**Reduction of bleeding is a primary goal during hepatic resection, as major blood loss is a pre-dominant factor for patient's outcome. Reduction of CVP as currently performed may have negative effects on kidney function and tissue perfusion and bears the risk to result in severe hemodynamic instability in case of intraoperative hemorrhage. For this reason, the present prospective, randomized trial evaluates the necessity of low central venous pressure (< 5mmHg) during LLR with an elevated pneuomeritoneum.**
**This is the first randomized trial in laparoscopic liver surgery investigating the necessity of low CVP (< 5mmHg) by anaesthesiological CVP reduction via fluid restriction for bleeding reduction during hepatic resections. Its reliable and comparable data may support evidence-based decision making within the wide range of existing strategies for reduction of intraoperative bleeding during liver resection. While the primary endpoint is intraoperative blood loss a set of general and surgical variables will be analysed to evaluate efficacy and safety of both methods.**

## Do you plan to share individual participant data with other researchers?

**Do you plan to share individual participant data with other researchers?**

**No**

**Description IPD sharing plan**

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00021748**
- Date of Registration in DRKS: **2020/06/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2020-575N , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Patients with elective laparoscopic liver resection**
- ICD10: **C22 - Malignant neoplasm of liver and intrahepatic bile ducts**
- ICD10: **C78.7 - Secondary malignant neoplasm of liver and intrahepatic bile duct**
- ICD10: **D13.4 - Benign neoplasm: Liver**
- ICD10: **C22.1 - Malignant neoplasm: Intrahepatic bile duct carcinoma**

## Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Group A (Control group) - LLR with central venous pressure reduction (< 5mmHg)</style>
- Arm 2: **Group B (Experimental group) - LLR without central venous pressure reduction**

## Characteristics

- Study Type: **Interventional**

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- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Intraoperative blood loss [mL]**

### Secondary Outcome

**• Blood loss during liver transection**
**• Number of patients requiring transfusions**
**• Operation time**
**• Conversion rate to open hepatic resections**
**• Transecetion time**
**• Need for additional inflow control**
**• Intraoperative complications**
**• Postoperative length of stay**
**• Biochemical blood value tests**
**• Resection margines**
**• Perioperative morbidity and mortality**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Chirurgische Klinik, Mannheim**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/07/09**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**• Elective LLR**
**• Age equal or greater than 18 years**
**• Written informed consent**

### Exclusion criteria

**• Extrahepatic resection required based on preoperative imaging**
**• Expected lack of compliance**
**• Child B or C liver cirrhosis**
**• Atrial fibrillation (impossibility to validly measure CVP via central venous line)**
**• Impaired mental state or language problems**

## Addresses

■ **Primary Sponsor**

**Universitätsmedizin Mannheim - Chirurgische Klinik**
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## Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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## Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

## Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*